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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,466	04/26/2001	Hiroyasu Kokubo	35576/233803	8005

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,466	KOKUBO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9,11,13-20 and 31-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9,11,13-20 and 31-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Humera N. Sheikh
Humera N. Sheikh
Primary Examiner
TC-1600

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action and Applicant's Arguments/Remarks, both filed 07/13/06 is acknowledged.

Claims 6-9, 11, 13-20 and 31-47 are pending in this action. Claims 1-5, 10, 12 and 21-30 have previously been cancelled. Claims 6-9, 11, 13-20 and 31-47 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6-9, 11, 13-17 and 31-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270) in view of Dempski *et al.* (U.S. Pat. No. 3,409,570).

The instant invention is drawn to a solid preparation coated with a multi-colored continuous film coating layer, prepared by the process of coating a solid preparation with a continuous film coating layer having one or more colorants; and exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

Hampton *et al.* ('270) teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

The multiple characteristic tablet comprises different color sections, which includes a color demarcation line (22) extending traversely between the halves (14 & 18) of the core. The core (12) is preferably coated with a clear material (24). The coloring agents employed are conventional and any desired color combination could be employed (col. 3, lines 5-38).

A feature of the invention is to coat the bi-layer, two-colored tablet with a single coating of gelatin or a film-forming polymeric substance, which will simulate the appearance, and function of the gelatin capsule. Suitable film-forming materials include methylcellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, ethylcellulose, various derivatives of methacrylic acids and methacrylic acid esters, and cellulose acetate phthalate (col. 5, lines 37-49). The coating of the film-forming polymer may be applied in several ways, such as by using conventional coating pans. Spray guns or other suitable atomizing equipment may be introduced into the coating pans to provide spray patterns conducive to rapid and uniform coverage of the tablet bed. The coating material is sprayed until the tablets are uniformly coated to the desired thickness and desired appearance of the tablet (col. 5, line 59 – col. 6, line 15).

The examples at columns 7-9 demonstrate two-colored, bi-layered capsule-shaped tablets. For instance, Example 1 demonstrates a bi-layered capsule-shaped tablet made from two separate layers, which were compressed together on a tablet press to form a tablet with an appearance similar to a capsule's appearance.

The instant claims are drawn to a solid preparation coated with a multi-colored continuous film coating layer prepared by coating a solid preparation with a continuous film-coating layer having one or more colorants; and exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

While Hampton *et al.* teach a two-colored, bi-layered tablet formulation consisting of a first and second different coloring agent, wherein the tablet is provided with a single continuous coating layer and film-forming agents, Hampton *et al.* do not teach 'exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration'.

Dempski *et al.* ('570) teach stabilization of dyes in a film coating material, whereby a colored pill or tablet is provided that retains its colorful appearance during prolonged exposure to sunlight or ultra-violet radiation. Dempski *et al.* teach stabilization of coloring agents and particularly, a dye containing film-coating material whose color intensity is not adversely effected by sunlight or ultra-violet light (UV light) (see reference column 1, lines 1-43). According to Dempski *et al.*, the incorporation of certain agents into a colorful film forming composition suitable for coating products, inhibits the fading of the color contained therein, when said film coating is exposed to sunlight or ultra-violet light. Stabilization can be achieved

by incorporating agents such as polyvinylpyrrolidone (PVP) or copolymers of vinylpyrrolidone, for example (col. 1, lines 44-56).

Dempski *et al.* also teach that to achieve market acceptance of certain products, it is sometimes desirable to color pills, tablets or other shaped cores and the like so as to enhance their physical appearance. This renders the product more acceptable for therapeutic administration. For the same reason, coloring matter must resist the effects of sunlight and ultraviolet radiation (col. 1, lines 25-38).

The examples at columns 3-5 demonstrate various tablet formulations, wherein the tablets were exposed to light sources. Example 1, at column 3 for instance, demonstrates preparation of a tablet whereby samples of a finished tablet were exposed to intense ultraviolet radiation from an ultraviolet lamp for 72 hours. Table 1 presents the results of samples that were exposed to the ultraviolet light and also presents results of samples that were protected from the UV exposure. The visually observable color characteristics are shown in the Table.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dye coating material stabilization methods, which comprise the step of exposing pills or tablets to sunlight or ultraviolet radiation taught by Dempski *et al.* within the multi-characteristic, bi-layered, two-color tablet of Hampton *et al.* if one would desire a color change effect observed in the tablet. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Dempski *et al.* teach and recognize that visual effects are obtained in tablets upon exposure with sunlight or ultraviolet radiation, such as fading and discoloration of tablet, as well as differences in the levels of color intensity of tablets. The

expected result would be an enhanced, multi-colored continuous coating layer having different colors along the body of the tablet for a pleasing colorful appearance for the consumer.

A product is being claimed in which the solid preparation comprises more than one distinct coloring agent. It is the position of the Examiner that the prior art expressly teaches a two-colored, bi-layered tablet formulation consisting of a first and second different coloring agent, wherein the tablet is provided with a single continuous coating layer and film-forming agents. The prior art also demonstrates the teaching of irradiating pills or tablets, which result in distinct coloring along the length of the tablet or pill. The instant claims are product claims and it is the patentability of the product that must be established, *per se*. Applicants have not demonstrated any unexpected or surprising results that accrue from the multi-colored, continuous film coating layer as claimed. The prior art recognizes and teaches a tablet that is multi-colored and has two layers that provide for distinct colors with different color sections, provided for easy recognition of the tablet and teaches the concept that the exposure of tablets to radiation, results in fading or discoloration of tablets.

Claims 18-20 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270) in view of Dempski *et al.* (U.S. Pat. No. 3,409,570) as applied to claims 6-9, 11, 13-17 and 31-44 above, and further in view of Hoover *et al.* (US Pat. No. 5,464,631).

Hampton *et al.* ('270), as discussed above, teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear

coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

Hampton *et al.* teach color demarcation lines on the tablet. Hampton *et al.* do not teach the inclusion of patterns comprising logos, bar codes or letters.

Hoover *et al.* ('631) teach a two-colored medicament dosage form having embossed or debossed letters, logos, symbols and the like on the surface of the dosage form (see reference column 4, lines 37-44).

It would have been obvious to use the combined teachings of Hoover *et al.*, who teaches a two-colored medicament comprising embossed letters, logos, symbols and the like, within the formulation of Hampton *et al.* who teaches a two-colored tablet with distinct color demarcations because Hoover *et al.* teach that the embossed letters, logos and symbols provide for visual perception, brand name recognition and an aesthetic appearance of the dosage form. The expected result would be a distinct, visually improved solid dosage form for easier brand recognition.

Response to Arguments

Applicant's arguments filed 07/13/06 have been fully considered but were not found to be persuasive.

Firstly, Applicant argued in regards to the 35 U.S.C. §103(a) rejection of claims 6-9, 11, 13-17 and 31-44 over Hampton et al. (US 5,089,270) stating, "Hampton describes a multi-colored tablet that is coated with a clear coating. The multi-coloration is achieved by combining

a first powder material containing a first coloring agent with a second powder material containing a second coloring agent. The two powders are compressed to form a solid tablet having a demarcation line between the first material and the second material. The two-colored tablet is subsequently coated with a clear gelatin layer through which the color components are visible. The gelatin layer is clear and is not multi-colored. The two-color sections comprise the core of the tablet and are not part of the coating. Dempski generally describes a method and dye for color stabilizing a film coating composition on a tablet or pill so that the colored film coating resists discoloration or fading when exposed to sunlight or ultraviolet light. The Office Action alleges that it would have been obvious to incorporate the dye coating material stabilization methods as taught in Dempski with the bi-layered, two-colored tablet of Hampton to produce the claimed invention.

The combination of Hampton and Dempski fails to teach the claimed invention. A tablet having the structural features recited in Claims 31 and 33 is not disclosed or suggested by the references. Hampton teaches a multi-colored core; not a multi-colored coating. Dempski specifically teaches the use of a color-stabilized dye to prevent discoloration or speckling in the film coating. As a result, a tablet utilizing the color stabilization dye of Dempski would not have a multi-colored film coating. Rather, such a tablet would have the multi-colored core of tablet of Hampton and an outer coating that is colored according to the dye that is part of the coating of Dempski. Indeed, Dempski teaches a coating that includes a dye and a compound that stabilizes the color of the coating so that the coating does not change color. See column 1, lines 44 - 56. Thus, the combination of Hampton and Demski fails to teach the claimed invention because they do not disclose a solid preparation having a continuous multi-colored film-coating layer."

Applicant's arguments have been fully considered but were not found to be persuasive. Admittedly, while Hampton teach a multi-colored core and not a multi-colored coating, the Dempski reference was relied upon to demonstrate dye stabilization coatings wherein the pills or tablets are exposed to radiation. Radiation sources include sunlight or ultraviolet light (UV light). While the Dempski reference teaches a coating that includes a dye and a compound that stabilizes the color of the coating so that the coating does not change color, the Dempski reference sufficiently demonstrates the teaching that various effects, such as fading and discoloration are obtained upon exposure of tablets to radiation, such as sunlight or ultraviolet light. Thus, the Dempski reference establishes the same concept of providing multicolored continuous coating layers, (i.e., faded or discolored) obtained by exposing the pills or tablets to radiation sources.

Applicant argued, "There is no teaching or suggestion in Hampton or Dempski of how to prepare a continuous coating having two different colorations. According to Hampton, the coloring agents are contained in the first and second powders used to make the body of the tablet rather than in a coating layer. In fact, Hampton's specific description of a clear coating layer teaches away from the recited different colorations in the multi-colored coating layer. Dempski teaches that exposure to sunlight or ultraviolet light results in fading or speckling. There is no disclosure in Dempski on how to make a coating having first and second parts of different coloration or controlling the exposure of UV radiation to different parts of the coating. In contrast, the claimed invention recites that parts of the solid preparation are exposed to radiation that results in a different coloration in the part of the coating that is exposed to the radiation.

Applicant's arguments have been fully considered but were not found to be persuasive. While the instant independent claims entail product-by-process claims, it is the patentability of the product that must be established. In this instance, the prior art in combination teaches a similar product that can include different colorations in the coating layer. As noted above, while Dempski do not teach a multi-colored coating layer, the secondary reference of Dempski was relied upon to establish that exposing pills or tablets to various radiation sources, results in faded or discolored pills/tablets, thus indicating presence of multiple colors along the tablet. Moreover, Examiner notes that the instant claims are very broad and vague in terms of radiation intensities or amounts; the claims simply recite 'first' and 'second' amounts of radiation. Thus, the generic teachings of Dempski are amply sufficient to read on the broad, instant claims.

Applicant argued, "There is no motivation to modify Hampton's clear coating layer and to provide differences in coloration in the coating layer. Hampton clearly teaches that the differences in coloration arise from the core not the outer coating. Dempski on the other hand, clearly teaches the prevention of discoloration in the coating using a dye stabilization compound. Thus, Dempski actually teaches how to make a tablet having a mono-colored coating layer, and does not provide motivation for producing a multi-colored tablet, let alone a multi-colored coating layer. Thus, neither Hampton nor Dempski provide any motivation that would lead one of ordinary skill in the art to combine their respective teachings.

These arguments were not persuasive. Ample motivation has been supplied by Dempski since the reference recognizes and teaches that discoloration and fading of tablets occur upon prolonged exposure to radiation. While Dempski teaches preventing of discoloration and fading by application of dye stabilization compounds, the reference vividly teaches the generic concept

that fading or discoloration can be obtained by exposing the pills or tablets to radiation sources. Thus, proper and ample motivation has been supplied by the secondary reference of Dempski.

Applicant argued, "Dempski specifically teaches fading or discoloration due to ultraviolet exposure as being undesirable. Specifically, Dempski states that "[a] faded or speckled pill or tablet can have an unpleasant psychological effect .... " See column 1, lines 32 - 33. Therefore, one of ordinary skill in the art would not be motivated to expose the tablet/pill of Hampton to ultraviolet light to produce a multi-colored tablet. In combining Hampton and Dempski, the Examiner has ignored the teachings in the references that teach away from the claimed invention and teach away from the combination of Hampton and Dempski. However, "[it] is improper to combine references where the references teach away from their combination." See MPEP 2146. Assuming for purposes of argument that there was some proper basis for combining the teachings of Hampton and Dempski, the references still fail to teach Applicants' invention since neither Hampton alone nor Dempski alone or any combinations thereof teach a multicolored coating.

This argument was not persuasive. One of ordinary skill in the art reading the reference of Dempski would gather that the result of exposing tablets/pills to radiation would be fading or discoloration. Dempski was cited to show that it is well known in the art that exposing tablets/pills to radiation results in different or multiple colors (i.e., faded in one portion; solid color in other portion). The reference vividly recognizes the effects that radiation could have on tablets/pills upon exposure thereof.

Applicant argued, "Modifying Hampton to have the coating of Dempski would render Hampton's tablet unsatisfactory for its intended purpose because the color stabilization dye of

Dempski would prevent visualization of the multi-colored core of Hampton. One of ordinary skill in the art would not be motivated to modify the tablet described in Hampton to have the coating of Dempski because such a modification would render Hampton unsatisfactory for its intended purpose.

Applicant's argument has been fully considered, but was not persuasive. As delineated above, the secondary reference of Dempski was relied upon solely to demonstrate the effects that radiation has when exposed to tablets/pills. The tablets of Dempski, when exposed to UV light or sunlight would impart multiple colors to a tablet.

Applicant argued, "The Examiner has failed to understand the scope and contents of the prior art. As discussed above, Dempski teaches a dye coating that is stabilized; not a multicolored coating. Further, Dempski teaches that fading or discoloration of the coating is undesirable; this teaching was completely ignored by the Examiner. Hampton teaches a clear coating with a core that is multicolored; Hampton does not teach a multicolored coating. Second, the Examiner has failed to ascertain the differences between the prior art and the claimed invention. Hampton teaches a clear coating with a multicolor core. Dempski teaches a tablet having a coating that includes a dye to resist color fading. As noted above; neither Dempski nor Hampton teach a multicolored coating. In contrast, the claimed invention recites a tablet having a multicolored continuous coating, which is not taught in Hampton or Dempski. Thus, the Examiner has failed to compare the actual teachings of the references to the claims."

Admittedly, while Hampton teach a multi-colored core and not a multi-colored coating, the Dempski reference was relied upon to demonstrate dye stabilization coatings wherein the pills or tablets are exposed to radiation. While the Dempski reference teaches a coating

comprised of dye stabilization compounds to prevent significant color change, the Dempski reference sufficiently demonstrates the teaching and generic concept that various effects, such as fading and discoloration are obtained upon exposure of tablets to radiation, such as sunlight or ultraviolet light. Thus, the Dempski reference establishes the same concept of providing multicolored continuous coating layers, (i.e., faded or discolored) obtained by exposing the pills or tablets to radiation sources.

Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 18-20 and 45-47 over Hampton ('270) in view of Hoover (US 5,464,631) stating, "Hoover describes a caplet wherein a caplet core is encapsulated in a gelatin capsule. The caplet and capsule are of two distinct colors so that the resulting caplet has two colors. Hoover further states that "[i]nsertion of the caplet within one-half of a gelatin capsule also allows for the visual perception of embossed or debossed letters, logos, symbols, and that like that may be placed on the surface of the caplet." See column 4, lines 37-44. (emphasis added). In contrast, the patterns recited in the present claims are part of the coating and are not printed or adhered to the surface of the coating. This is a completely different structure than the caplet of Hoover."

Applicant's arguments have been thoroughly considered, but were not found to be persuasive. Applicant employs patterns, such as logos, letters and bar codes for easier identification and recognition of tablets. The reference of Hoover et al. was relied upon for their teaching that it is known in the art to employ patterns that include logos, bar codes or letters in multi-colored tablet formulations. The Hoover reference teaches that the embossed letters, logos and symbols provide for visual perception, brand name recognition and an aesthetic appearance of the dosage form (see Hoover col. 4, lines 37-43). While the caplet of Hoover provides for

logos and the like on the surface of the caplet, the reference demonstrates the same purpose as desired by Applicant, which is to provide easier recognition as well as an aesthetically pleasing appearance of tablets.

Given the teachings of the prior art delineated above, it is the position of the Examiner that the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

October 02, 2006

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